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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,306	08/25/2000	Cameron J. Koch	UPN-3904	6906

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EXAMINER

WRIGHT, SONYA N

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 04/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/648,306

Applicant(s)

KOCH ET AL.

Examiner

Sonya Wright

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-22 and 27-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-22 and 27-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to Applicant's Request for Reconsideration filed January 7, 2002. Claims 20-22 and 27-32 are pending in this application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-22 and 27-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-19 of U.S. Patent No. 5,540,908 (Koch et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. Koch et al. teach instant claim 20 in claim 14, however, the difference between Koch et al., claim 14, and instant claim 20, is that in Koch et al., claim 14, R₂ is an alkyl group with the formula CHXCX₂CY₃ (wherein X is halogen or hydrogen) and in instant claim 20, R₂ has the formula CH₂CX₂CHX₂ (wherein X is halogen or hydrogen). Formula R₂ in instant claim 20 is obvious over formula R₂ of Koch et al. (claim 14) because of the structural similarities between the formulas.

In claim 15, Koch et al. teach instant claim 21, and the difference between the two claims is that in claim 15 Koch et al. mention PET as well as magnetic resonance imaging, while instant claim 21 only mentions PET. Claim 18 in Koch et al. teaches instant claim 22, and claim 14 in Koch et al. teach instant claims 27-32.

Claim Rejections - 35 USC § 103

Claims 20-22 and 27-32 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over US Patent 5,540,908, which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the application, it constitutes prior art under 35 U.S.C. 102(e).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20-22 and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,540,908, Koch et al..

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim a method for detecting tissue hypoxia in a mammal, and Koch et al. teach a method for detecting tissue hypoxia in a mammal. Koch et al. teach instant claims 20,-22 and 27-32 in column 1, lines 24-26, and column 6, lines 10-26. (Also see column 7, lines 20-29, for instant claims 20 and 21). Koch et al. teach the instant claims, when, in the instant claims, R₁ and R₂ are as defined.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the prior art and the instant claims is that the prior art teaches a genus that encompasses Applicants' claims.

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)

One of ordinary skill in the art would be motivated to use the teachings of Koch et al. to use the instant compounds in detecting tissue hypoxia in the expectation that all compounds under the genus would have similar methods of use. Koch et al. gives guidance to prepare the instant compounds in line 6, columns 22 and 23, where the preferred number of halogen atoms is about 6 and the preferred halogen atom is fluorine.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-22 and 27-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,

3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The claims are drawn to "a method for detecting tissue hypoxia in a mammal comprising: introducing into the mammal a compound having the formula (given) wherein R_1 is CH_2 and R_2 has the formula $CH_2CX_2CHX_2$ wherein X is halogen or hydrogen . . . and imaging the portion of the mammal containing the tissue". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. On page 12 of Applicant's specification, Applicant gives guidance that in order for the instant compounds to be used in magnetic resonance imaging, F^{19} is required (see lines 10 and 11) and in order for the compounds to be used in positron emission tomography, F^{18} is required (see lines 11 and 12). Therefore, claim 20 is rendered inoperable without F^{19} or F^{18} . The scope of the claims is broader than the enabling disclosure. Applicant gives limited examples to support the claims. The art pertaining to detecting tissue hypoxia remains highly unpredictable. The level or ordinary skill in the art is high. Therefore, based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

It is suggested that applicants limit claim 20 to compounds containing F¹⁹ and F¹⁸ in order to obviate the rejection under 35 U.S.C. 112 first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "introducing into a mammal" is indicative of an in vivo method. However, the term "introducing" implies that either an in vivo or an in vitro method is being claimed. It is requested that Applicants delete "introducing" and insert – administering--.

Response to Arguments

Applicant's arguments filed January 7, 2002 have been fully considered but they are not persuasive. Applicant argues that the test for double patenting is whether or not subject matter of patent claims is obvious from subject matter of claims at issue and that the Office Action points to no evidence in the 908 patent claims, the only proper evidence, to support the rejection. However, in column 6, lines 21-13, Koch et al. teach that "the R₂ substituent is an alkyl group containing 1 to 6 carbons, and preferably having up to about 6 halogen atoms". The teachings of Koch et al. encompass the R₂ substituent, -CH₂-CX₂-CHX₂, wherein X is hydrogen or a halogen. Therefore, the obvious double patenting rejection is maintained.

With regard to the rejection under 35 U.S.C. 103, Applicant argues that the Office Action points to no teaching found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to combine or modify the teachings of the prior art to produce the claimed invention. However, in column 6, lines 21-23, Koch et al. teach that "the R_2 substituent is an alkyl group containing 1 to 6 carbons, and preferably having up to about 6 halogen atoms". Applicant argues that the Office Action erroneously suggests that the '908 patent at column 6, lines 22 and 23 "gives guidance to prepare the instant compounds". Applicants argue that the genus disclosed in the '908 patent contains numerous variables and there is nothing in the disclosure suggesting that one should select the variables that would result in the claimed compounds. However, the structure of Applicant's compounds and the structure of the '908 patent compounds is similar. The only variation that Applicant argues differentiates their compounds from those of the '908 patent is the definition of R_2 in the instant claims. However, the '908 patent teaches a preferred embodiment of R_2 which is similar to the compounds of Applicant in line 6, columns 22-26. Therefore, Applicant's compounds are obvious over those of the '908 patent.

If Applicant overcomes the rejections under 35 U.S.C. 112 first and second paragraphs, the obviousness double patenting rejection, and the rejection under 35 U.S.C. 103 will also be overcome.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-

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4539. The examiner can normally be reached on Monday-Friday from 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

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Celia Chang

Primary Examiner

Group 1600

Sonya Wright

March 28, 2002